

Europäisches Patentamt
European Patent Office
Office européen des brevets



(11) **EP 1 169 972 A1**

(12) **EUROPEAN PATENT APPLICATION**

(43) Date of publication:
09.01.2002 Bulletin 2002/02

(51) Int Cl.7: **A61B 18/14**

(21) Application number: **01305844.1**

(22) Date of filing: **06.07.2001**

(84) Designated Contracting States:
**AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU
MC NL PT SE TR**
Designated Extension States:
AL LT LV MK RO SI

(72) Inventors:
• **Mest, Robert A.**
Long Beach, California 90808 (US)
• **Nakagawa, Hiroshi**
Edmond Oklahoma 73003 (US)

(30) Priority: **07.07.2000 US 611617**

(74) Representative: **Mercer, Christopher Paul et al**
Carpmaels & Ransford 43, Bloomsbury Square
London WC1A 2RA (GB)

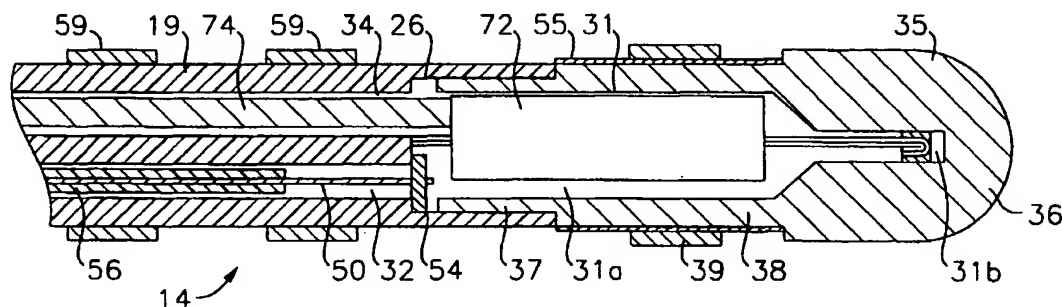
(71) Applicant: **Biosense Webster, Inc.**
Diamond Bar, California 91765 (US)

(54) **Mapping and ablation catheter**

(57) A catheter for mapping and ablating comprises an elongated flexible body having a distal region and at least one lumen extending therethrough. A tip electrode is mounted on the distal region. The tip electrode has an exposed distal region having proximal and distal ends and an isolated region proximal to the exposed distal region. The isolated region has an outer surface pro-

vided with an electrically insulating and thermally conductive layer. A second electrode is mounted on the isolated region of the tip electrode. This mapping and ablation electrode arrangement provides discrete recording of electrical signals due to the relatively small exposed distal region while allowing the creating of larger lesions due to the large thermal mass provided by the isolated region.

FIG. 3A



EP 1 169 972 A1

Description

FIELD OF THE INVENTION

[0001] The present invention is directed to a catheter for electric diagnosis and treatment of the heart, and more particularly to a catheter for mapping and ablation.

BACKGROUND OF THE INVENTION

[0002] Electrode catheters have been in common use in medical practice for many years. They are used to stimulate and map electrical activity in the heart and to ablate sites of aberrant electrical activity.

[0003] In use, the electrode catheter is inserted into a major vein or artery, e.g., femoral artery, and then guided into the chamber of the heart which is of concern. Once the catheter is positioned within the heart, the location of aberrant electrical activity within the heart is then located.

[0004] One location technique involves an electrophysiological mapping procedure whereby the electrical signals emanating from the conductive endocardial tissues are systematically monitored and a map is created of those signals. By analyzing that map, the physician can identify the interfering electrical pathway. A conventional method for mapping the electrical signals from conductive heart tissue is to percutaneously introduce an electrophysiology catheter (electrode catheter) having mapping electrodes mounted on its distal extremity. The catheter is maneuvered to place these electrodes in contact with or in close proximity to the endocardium. By monitoring the electrical signals at the endocardium, aberrant conductive tissue sites responsible for the arrhythmia can be pinpointed.

[0005] For mapping, it is desirable to have a relatively small mapping electrode. It has been found that smaller electrodes record more accurate and discrete electrograms. Additionally, if a bipolar mapping arrangement is used, it is desirable that the two electrodes of the mapping arrangement be in close proximity to each other and that they be similar in size to produce more accurate and useful electrograms.

[0006] Once the origination point for the arrhythmia has been located in the tissue, the physician uses an ablation procedure to destroy the tissue causing the arrhythmia in an attempt to remove the electrical signal irregularities and restore normal heart beat or at least an improved heart beat. Successful ablation of the conductive tissue at the arrhythmia initiation site usually terminates the arrhythmia or at least moderates the heart rhythm to acceptable levels.

[0007] A typical ablation procedure involves providing a reference electrode, generally taped to the skin of the patient. RF (radio frequency) current is applied to the tip electrode, and current flows through the media that surrounds it, i.e., blood and tissue, toward the reference electrode. The distribution of current depends on the

amount of electrode surface in contact with the tissue as compared to blood, which has a higher conductivity than the tissue. Heating of the tissue occurs due to its electrical resistance. The tissue is heated sufficiently to cause cellular destruction in the cardiac tissue resulting in formation of a lesion within the cardiac tissue which is electrically non-conductive. During this process, heating of the electrode also occurs as a result of conduction from the heated tissue to the electrode itself. If the electrode temperature becomes sufficiently high, a thin transparent coating of dehydrated blood protein can form on the surface of the electrode. If the temperature continues to rise, this dehydrated layer can become progressively thicker, resulting in char and/or thrombus on the electrode surface. The creation of char and thrombus is unsafe, as the char and thrombus can be dislodged from the electrode during the procedure or during removal of the catheter after the procedure.

[0008] In clinical practice, it is desirable to reduce or eliminate the formation of char and thrombus and, for certain cardiac arrhythmias, to create larger and/or deeper lesions. One method for accomplishing this end is to monitor the temperature of the ablation electrode and to control the RF current delivered to the ablation electrode based on this temperature. If the temperature rises above a preselected value, the current is reduced until the temperature drops below this value.

[0009] Another method for determining whether char and thrombus is forming is by monitoring the impedance. Specifically, because dehydrated biological material has a higher electrical resistance than endocardial tissue, impedance to the flow of electrical energy into the tissue also increases. A significant impedance rise thus indicates the formation of char and/or thrombus. With a relatively large electrode, e.g., an 8 mm electrode, an impedance rise from char and thrombus formation may not be easily detected because the char and thrombus is formed over a relatively small percentage of the total surface area of the electrode. In contrast, if the electrically active surface area of the electrode is relatively small, char and thrombus will form over a relatively larger area of the electrode, making detection by impedance measurements easier.

[0010] The cooling effect of the blood on the electrode is dependent on the thermal properties of the ablation electrode, and in particular its surface area. Typically ablation electrodes are relatively long, most commonly at least about 4 mm and up to about 8 mm, to provide sufficient surface area for cooling. However, such electrodes are less suitable for mapping because, as discussed above, more accurate electrograms can be obtained with a smaller mapping electrode. It is desirable for electrophysiologists use the same catheter for mapping and ablation during a single procedure because, once a site is identified with a high resolution mapping electrode catheter as a target for therapy, it would be difficult to locate that site again with another catheter, particularly where the other catheter has a larger tip

electrode. Accordingly, a need exists for an electrode catheter that has a relatively small surface area for enhanced mapping, but has good thermal properties for enhanced cooling during ablation.

[0011] Another disadvantage of typical ablation electrodes is that it is sometimes difficult to accurately predict lesion size because the lesion size can vary depending on the orientation of the ablation electrode. For example, typically a 7 French catheter (having an outer diameter of just over 2 mm) is provided with an ablation tip electrode at its distal end having a length ranging from about 4 mm to about 8 mm. If the ablation electrode is provided in perpendicular relation to the tissue, a relatively small surface area of the electrode is in contact with the tissue. In contrast, a relatively larger surface area would be in contact with the tissue if the ablation electrode were in a generally parallel relationship to the tissue, i.e., if the ablation electrode were positioned on its side. It is often difficult for the physician to determine the precise orientation of the tip electrode relative to the tissue because the tissue is not visible with fluoroscopy. The size of the lesion is often related to the amount surface area in contact with the tissue. As a result, there is less predictability in lesion size.

[0012] Thus, although it is desirable to have a relatively long electrode for cooling purposes, it is desirable to have a relatively small electrically active surface area for obtaining more discrete electrograms, for more accurately detecting char and thrombus formation, and for enhancing the predictability of lesion size.

SUMMARY OF THE INVENTION

[0013] The invention is directed to an improved catheter for mapping and ablation. The catheter has an electrode arrangement at its distal end that provides more accurate mapping capability than a typical ablation electrode by having a relatively small surface area in contact with the tissue. Additionally, the electrode provides for better cooling than a typical mapping electrode by having an electrically insulating and thermally conductive region.

[0014] In one embodiment, the catheter comprises an elongated flexible body having a distal region and at least one lumen extending therethrough. A tip electrode is mounted on the distal region. The tip electrode has an exposed distal region having proximal and distal ends and an isolated region proximal to the exposed distal region. The isolated region has an outer surface provided with a electrically insulating and thermally conductive layer. A second electrode, preferably a ring electrode, is mounted on the isolated region of the tip electrode.

[0015] In another embodiment, the invention is directed to a catheter comprising an elongated flexible body having proximal and distal ends and at least one lumen extending therethrough. A tip section comprising a flexible tubing that is more flexible than the catheter body

is mounted at the distal end of the catheter body. The flexible tubing has proximal and distal ends and at least one lumen extending therethrough. A tip electrode is mounted on the distal end of the flexible tubing. The tip electrode has an exposed distal region having proximal and distal ends and an isolated region proximal to the distal region. The isolated region has an outer surface provided with an electrically insulating and thermally conductive layer. A ring electrode is mounted on the isolated region of the tip electrode.

[0016] The catheters of the present invention provide a tip electrode with an exposed region smaller than standard ablation electrodes. Yet the electrode provides enhanced cooling over standard mapping electrodes due to the isolated region having an electrically insulating and thermally conductive coating. Additionally, the second or ring electrode, which is mounted directly on the tip electrode, can be closely-spaced to the exposed region of the tip electrode to allow close bipolar electrogram recording, thus providing more discrete electrograms.

[0017] In another embodiment, the invention is directed to a catheter comprising an elongated flexible body having a distal region and at least one lumen extending therethrough. A tip electrode is mounted on the distal region. The tip electrode has an exposed distal region having proximal and distal ends, a length and an outer diameter. The ratio of the length to the outer diameter ranges from about 0.8:1 to about 1.2:1. The tip electrode also has an isolated region proximal to the exposed distal region. The isolated region has an outer surface provided with an electrically insulating and thermally conductive layer. These uniform dimensions provide a generally constant contact area between the exposed region of the tip electrode and the heart tissue, irrespective of the orientation of the tip section relative to the heart tissue. As a result, more predictable lesion sizes can be achieved.

DESCRIPTION OF THE DRAWINGS

[0018] These and other features and advantages of the present invention will be better understood by reference to the following detailed description when considered in conjunction with the accompanying drawings wherein:

FIG. 1 is a side view of an embodiment of the catheter of the invention.

FIG. 2 is a side cross-sectional view of a catheter body according to the invention, including the junction between the catheter body and tip section.

FIG. 3A is a side cross-sectional view of a catheter tip section showing the lumens for the sensor cable and puller wire.

FIG. 3B is a side cross-sectional view of FIG. 3A showing the lumens for the sensor cable and thermocouple and electrode lead wires.

FIG. 3C is an enlarged view of the distal end of the thermocouple mounted in the tip electrode of the catheter of FIGs. 3A and 3B.

FIG. 4 is a longitudinal cross-sectional view of the tip section illustrated in FIGs. 3A and 3B.

FIG. 5 is a side view of an electrode arrangement in accordance with the invention.

DETAILED DESCRIPTION

[0019] In a particularly preferred embodiment of the invention, there is provided a steerable catheter having two electrodes for making bipolar measurements. As shown in FIGs. 1 and 2, catheter 10 comprises an elongated catheter body 12 having proximal and distal ends, a tip section 14 at the distal end of the catheter body 12, and a control handle 16 at the proximal end of the catheter body 12.

[0020] With reference to FIG. 2, the catheter body 12 comprises an elongated tubular construction having a single, axial or central lumen 18. The catheter body 12 is flexible, i.e., bendable, but substantially non-compressible along its length. The catheter body 12 can be of any suitable construction and made of any suitable material. A presently preferred construction comprises an outer wall 22 made of a polyurethane, or PEBAX. The outer wall 22 comprises an imbedded braided mesh of high-strength steel, stainless steel or the like to increase torsional stiffness of the catheter body 12 so that, when the control handle 16 is rotated, the tip section 14 of the catheter 10 will rotate in a corresponding manner.

[0021] The outer diameter of the catheter body 12 is not critical, but is preferably no more than about 8 french, more preferably about 7 french. Likewise the thickness of the outer wall 22 is not critical, but is thin enough so that the central lumen 18 can accommodate a puller wire, lead wires, and any other wires, cables or tubes. The inner surface of the outer wall 22 is lined with a stiffening tube 20, which can be made of any suitable material, such as polyimide or nylon. The stiffening tube 20, along with the braided outer wall 22, provides improved torsional stability while at the same time minimizing the wall thickness of the catheter, thus maximizing the diameter of the central lumen 18. The outer diameter of the stiffening tube 20 is about the same as or slightly smaller than the inner diameter of the outer wall 22. Polyimide tubing is presently preferred for the stiffening tube 20 because it may be very thin walled while still providing very good stiffness. This maximizes the diameter of the central lumen 18 without sacrificing strength and stiffness.

[0022] One preferred catheter has an outer wall 22 with an outer diameter of from about 0.090 inch to about 0.098 inch and an inner diameter of from about 0.061 inch to about 0.065 inch and a polyimide stiffening tube 20 having an outer diameter of from about 0.060 inch to about 0.064 inch and an inner diameter of from about 0.051 inch to about 0.056 inch. As would be recognized

by one skilled in the art, the catheter body construction can be modified as desired. For example, the stiffening tube can be eliminated.

[0023] As shown in FIGs. 3A, 3B, 4 and 5, the tip section 14 comprises a short section of tubing 19 having three lumens 30, 32 and 34. The tubing 19 is made of a suitable non-toxic material that is preferably more flexible than the catheter body 12. A presently preferred material for the tubing 19 is braided polyurethane, i.e., polyurethane with an embedded mesh of braided high-strength steel, stainless steel or the like. The outer diameter of the tip section 14, like that of the catheter body 12, is preferably no greater than about 8 french, more preferably about 7 french. The size of the lumens is not critical and can vary depending on the specific application. In a particularly preferred embodiment, the tip section 14 has an outer diameter of about 7 french (.092 inch) and the first lumen 30 and second lumen 32 are generally about the same size, each having a diameter of from about 0.020 inch to about 0.024 inch, preferably 0.022 inch, with the third lumen 34 having a slightly larger diameter of from about 0.032 inch to about 0.038 inch, preferably 0.036 inch.

[0024] A preferred means for attaching the catheter body 12 to the tip section 14 is illustrated in FIG. 2. The proximal end of the tip section 14 comprises an outer circumferential notch 24 that receives the inner surface of the outer wall 22 of the catheter body 12. The tip section 14 and catheter body 12 are attached by adhesive (e.g., polyurethane glue) or the like. Before the tip section 14 and catheter body 12 are attached, however, the stiffening tube 20 is inserted into the catheter body 12. The distal end of the stiffening tube 20 is fixedly attached near the distal end of the catheter body 12 by forming a glue joint (not shown) with polyurethane glue or the like. Preferably a small distance, e.g., about 3 mm, is provided between the distal end of the catheter body 12 and the distal end of the stiffening tube 20 to permit room for the catheter body 12 to receive the notch 24 of the tip section 14. A force is applied to the proximal end of the stiffening tube 20, and, while the stiffening tube 20 is under compression, a first glue joint (not shown) is made between the stiffening tube 20 and the outer wall 22 by a fast drying glue, e.g. Super Glue®. Thereafter a second glue joint (not shown) is formed between the proximal ends of the stiffening tube 20 and outer wall 22 using a slower drying but stronger glue, e.g., polyurethane.

[0025] At the distal end of the tip section 14 is a tip electrode 36. Preferably the tip electrode 36 has a diameter about the same as the outer diameter of the tubing 19. The tip electrode 36 can be made from any suitable material, such as platinum, gold, or stainless steel, and is preferably machined from platinum-iridium rod (90% platinum/10% iridium).

[0026] The tip electrode 36 has a total length preferably ranging from about 4 mm to about 14 mm, more preferably from about 6 mm to about 12 mm. As depicted in FIGs. 3A, 3B and 5, the tip electrode 36 comprises

an exposed region 35 at its distal end, a stem 37 at its proximal end, and a central region 38 interposed the exposed region 35 and the stem 37. The exposed region 35 has a length preferably ranging from about 1.5 mm to about 4.0 mm, more preferably from about 2.0 mm to about 3.0 mm, still more preferably from about 2.3 mm to about 2.5 mm, and an outer diameter preferably ranging from about 2.0 mm to about 3.0 mm, more preferably from about 2.3 mm to about 2.5 mm.

[0027] In a particularly preferred arrangement, the exposed region has a length similar to its diameter. Preferably the ratio of the length to the diameter ranges from about 0.8:1 to about 1.2:1, more preferably from about 0.9:1 to about 1.1:1. In a particularly preferred embodiment, the length of the exposed region is approximately equal to the diameter of the exposed region. Thus, for example, for a 7 French electrode catheter, the tip electrode preferably has a length and diameter equal to about 2.3 mm. With such a design, the surface area of the tip electrode (having a generally hemispherical distal end) is the same in the parallel orientation and in the perpendicular orientation. These uniform dimensions provide a generally constant contact area between the exposed region 35 of the tip electrode 36 and the heart tissue, irrespective of the orientation of the tip section 14 relative to the heart tissue. As a result, more predictable lesion sizes can be achieved.

[0028] The central region 38 has a length preferably ranging from about 2 mm to about 10 mm, more preferably from about 3 mm to about 8 mm, still more preferably from about 3.5 mm to about 6 mm. In the depicted embodiment, the outer diameter of the central region 38 is slightly less than the outer diameter of the exposed region 35, and is preferably from about 0.1 mm to about 0.3 mm lesser than less than the outer diameter of the exposed region. As described in more detail below, the central region 38 is provided with a covering and a ring electrode is mounted thereon. When the outer diameter of the central region 38 is slightly less than the outer diameter of the exposed region 35, the outer diameter of the ring electrode mounted thereon will generally correspond to the outer diameter of the exposed region. Alternatively, the outer diameter of the ring electrode (and optionally the outer diameter of the central region 38) can be greater than the outer diameter of the exposed region 35.

[0029] The stem 37 is provided for mounting of the tip electrode 36 onto the tubing 19 of the tip section 14. The stem has a length preferably ranging from about 1 mm to about 4 mm, more preferably from about 1.5 mm to about 2.5 mm, still more preferably about 2.0 mm. The outer diameter of the stem 37 is less than the outer diameter of the central region 38, and preferably ranging from about 1.5 mm to about 2.0. The dimensions of the stem 37 are not critical, so long as the stem can fit within the distal end of the tubing 19. A hole is drilled into the distal end of the tubing 19, and the proximal end of the stem 37 is glued into the hole, with polyurethane glue

or the like. Preferably the proximal end of the stem 37 does not contact the inside of the tubing 19 so that a slot 26 is provided therebetween, to assist in the anchoring of a puller wire discussed in more detail below.

[0030] Alternatively, the stem 37 can be eliminated, and the proximal end of the tip electrode 36 can be mounted onto the tubing 19 by any other suitable means known in the art. For example, the distal end of the tubing 19 can be inserted into an opening in this proximal end of the tip electrode 36, e.g., within the central region 38, and fixed in place with glue or the like.

[0031] The stem 37, central region 38, and exposed region 35 are generally solid with a blind hole 31 extending from the proximal end of the stem 37 part way into the exposed region 35. The blind hole 31 comprises a proximal section 31a having a first diameter and a distal section 31b having a second diameter less than the first diameter. The proximal section 31a has a length preferably ranging from about 5.5 mm to 6.0 mm, more preferably about 5.7 mm, and a diameter preferably ranging from about 1.0 mm to 1.5 mm, more preferably about 1.3 mm. The distal section 31b preferably begins at the proximal end of the exposed region 35 and extends into the exposed region 35 a distance such that the distal end of the hole does not extend out through the distal end of the exposed region, but is preferably within about 0.5 mm of the distal end of the exposed region. The diameter of the distal section 31b preferably ranges from about 0.3 mm to 0.7 mm, more preferably about 0.5 mm. Preferably the distal section 31b is designed so that a thermocouple or the like mounted therein, as discussed in more detail below, is generally in the center of the exposed region 35.

[0032] The central region 38 of the tip electrode 36 is provided with an electrically insulating and thermally conductive layer 55 over at least a portion, and preferably over all, of the outer surface of the central region 38. The electrically insulating and thermally conductive layer 55 is made of any suitable electrically insulating and thermally conductive material, including, but not limited to diamond, carbon, parylene, polyimide, polyester, polyurethane, epoxy, ceramic, and combinations thereof. The electrically insulating and thermally conductive layer 55 preferably has a thickness no greater than about 10 μm , more preferably ranging from about 0.5 μm to about 10 μm , still more preferably from about 1 μm to about 5 μm .

[0033] The insulating layer 55 can be applied by any suitable technique. For example, a layer of parylene can be applied by a deposition coating technique where the exposed region 35 of the tip electrode 36 is placed in a deposition chamber. The chamber functions to both hold the tip electrode 36 in place, as well as protect the exposed region 35 from exposure to parylene deposits. Alternatively, the insulating layer 55 may comprise a shrink-sleeve made of, for example, a thin polyester (e.g., about 0.00025 inch), or may comprise a thin coating of polyurethane or the like painted onto the surface of

the central region 38.

[0034] A ring electrode 39 is mounted on the central portion 38 of the tip electrode 36. The ring electrode 39 is slid over the electrically insulating layer 55 and fixed in place by glue or the like. The electrically insulating layer 55 insulates the tip electrode 36 from the ring electrode 39. The ring electrode 39 can be made of any suitable electrically-conductive material, such as platinum, gold, or stainless steel, and is preferably made from a platinum-iridium alloy (90% platinum/10% iridium). In the depicted embodiment, the ring electrode 39 is mounted near the distal end of the central portion 38 in close proximity to the exposed region 35. In this embodiment, the ring electrode 39 (i.e., the distal edge of the ring electrode) is preferably spaced apart from the exposed region 35 a distance no greater than about 2 mm, more preferably from about 0.2 mm to about 1.5 mm, more preferably from about 0.2 mm to about 0.5 mm. Alternatively, the ring electrode 39 can be positioned closer to the flexible tubing 19, in which case the ring electrode (i.e., the proximal edge of the ring electrode) is preferably spaced apart from the distal end of the tubing a distance no greater than about 2 mm. The ring electrode 39 has a width preferably ranging from about 0.4 mm to about 2.0 mm, more preferably from about 0.5 mm to about 1.5 mm, still more preferably from about 0.6 mm to about 1.0 mm. Preferably the outer diameter of the ring electrode 39 is the same as the outer diameter of the exposed region 35 of the tip electrode 36.

[0035] The tip electrode 36 and ring electrode 39 are each connected to a separate lead wire 44. The lead wires 44 extend through the first lumen 30 of tip section 14, the central lumen 18 of the catheter body 12, and the control handle 16, and terminate at their proximal end in an input jack (not shown) that may be plugged into an appropriate signal processing unit (not shown) and source of RF energy (not shown). The portion of the lead wires 44 extending through the central lumen 18 of the catheter body 12, control handle 16 and proximal end of the tip section 14 may be enclosed within a protective sheath 49, which can be made of any suitable material, preferably polyimide. The protective sheath 49 is preferably anchored at its distal end to the proximal end of the tip section 14 by gluing it in the first lumen 30 with polyurethane glue or the like.

[0036] The lead wires 44 are attached to the tip electrode 36 and ring electrodes 39 by any conventional technique. Connection of a lead wire 44 to the tip electrode 36 is accomplished, for example, by soldering the lead wire 44 into a first hole 47 located along the stem 37 of the tip electrode 36, as shown in FIG. 3B.

[0037] Connection of a lead wire 44 to the ring electrode 39 is preferably accomplished by first making a second hole 48 through the central region 38 of the tip electrode 36 and through the insulating layer 55. A lead wire 44 is then drawn through the hole 48. The ends of the lead wire 44 are then stripped of any coating and soldered or welded to the underside of the ring electrode

39, which is then slid into position over the hole 48 and fixed in place with polyurethane glue or the like.

[0038] Two additional ring electrodes 59 are mounted of the distal end the tip section 14. The ring electrodes 59 are slid over the flexible tubing 19 and fixed in place by glue or the like. The position and spacing of the additional ring electrode 59 are not critical. If desired, additional ring electrodes 59 may be used and can be positioned over the flexible tubing 19 of the tip section 14 in a similar manner.

[0039] A temperature sensing means is provided for the tip electrode 36 and, if desired, the ring electrodes 39 and/or 59. Any conventional temperature sensing means, e.g., a thermocouple or thermistor, may be used. A preferred temperature sensing means for the tip electrode 36 comprises a thermocouple formed by an enameled wire pair. One wire of the wire pair is a copper wire 41, e.g., a number 40 copper wire. The other wire of the wire pair is a constantan wire 45. The wires 41 and 45 of the wire pair are electrically isolated from each other except at their distal ends where they are twisted together, covered with a short piece of plastic tubing 58, e.g., polyamide, and covered with epoxy (as shown in FIG. 3c). The plastic tubing 58 is then attached in the distal section 31b of the blind hole 31 in the tip electrode 36, by polyurethane glue or the like. Alternatively, the wires 41 and 45 can be soldered into the distal section 31b.

[0040] The wires 41 and 45 extend through the second lumen 32 in the tip section 14 and through the central lumen 18 of the catheter body 12. Within the second lumen 32 and central lumen 18, the wires 41 and 45 extend through the protective sheath 49 with the lead wires 44. The wires 41 and 45 then extend out through the control handle 16 and to a connector (not shown) connectable to a temperature monitor (not shown).

[0041] Alternatively, the temperature sensing means may be a thermistor. A suitable thermistor for use in the present invention is Model No. AB6N2-GC 14KA 143E/37C sold by Thermometrics (New Jersey).

[0042] Additionally, a mechanism is provided for deflecting the tip section 14. In one embodiment, the mechanism comprises a puller wire 50 extending through the catheter body 12. The puller wire 50 is anchored at its proximal end to the control handle 16 and is anchored at its distal end to the tip section 14. The puller wire 50 is made of any suitable metal, such as stainless steel or Nitinol, and is preferably coated with Teflon® or the like. The coating imparts lubricity to the puller wire 50. The puller wire 50 preferably has a diameter ranging from about 0.006 to about 0.010 inch.

[0043] A compression coil 52 is situated within the catheter body 12 in surrounding relation to the puller wire 50. The compression coil 52 extends from the proximal end of the catheter body 12 to the proximal end of the tip section 14. The compression coil 52 is made of any suitable metal, preferably stainless steel. The compression coil 52 is tightly wound on itself to provide flex-

ibility, i.e., bending, but to resist compression. The inner diameter of the compression coil 52 is preferably slightly larger than the diameter of the puller wire 50. The Teflon® coating on the puller wire 50 allows it to slide freely within the compression coil 52. If desired, particularly if the lead wires 44 are not enclosed by a protective sheath 49, the outer surface of the compression coil 52 can be covered by a flexible, non-conductive sheath 46, e.g., made of polyimide tubing, to prevent contact between the compression coil 52 and any other wires within the catheter body 12.

[0044] The compression coil 52 is anchored at its proximal end to the proximal end of the stiffening tube 20 in the catheter body 12 by glue joint 51 and at its distal end to the tip section 14 by glue joint 53. Both glue joints 51 and 53 preferably comprise polyurethane glue or the like. The glue may be applied by means of a syringe or the like through a hole made between the outer surface of the catheter body 12 and the central lumen 18. Such a hole may be formed, for example, by a needle or the like that punctures the outer wall 22 of the catheter body 12 and the stiffening tube 20 which is heated sufficiently to form a permanent hole. The glue is then introduced through the hole to the outer surface of the compression coil 52 and wicks around the outer circumference to form a glue joint about the entire circumference of the compression coil 52.

[0045] The puller wire 50 extends into the second lumen 32 of the tip section 14. The puller wire 50 is anchored at its distal end to the distal end of the tip section 14 by an anchor 54. A preferred method for anchoring the puller wire 50 within the slot 26 is by soldering or welding the distal end of the puller wire 50 to an anchor 54, preferably formed from a small section of stainless steel ribbon or the like. The anchor 54 is displaced inside the slot 26 between the inside of the tubing 19 and the proximal end of the stem 37 in a transverse arrangement to the puller wire, forming a T-bar or anchor. Because the length of the anchor 54 is longer than the diameter of the second lumen 32, the anchor 54 cannot be pulled through the lumen 32. Alternatively, the puller wire 50 can be anchored in a blind hole in the tip electrode 36, as described, for example, in U.S. Patent No. 6,027,473, the disclosure of which is incorporated herein by reference. In another alternative, the puller wire 42 can be anchored to the side of the tip section 14, as described, for example, in EP-A-0 904 796,

the disclosure of which is incorporated herein by reference. Within the second lumen 32 of the tip section 14, the puller wire 50 extends through a plastic, preferably Teflon®, sheath 56, which prevents the puller wire 50 from cutting into the wall of the tubing 19 when the tip section is deflected.

[0046] A safety wire 57 extends through the catheter body 12 and is anchored at its distal end to the tip electrode 36. The safety wire 57 is preferably a Monell wire wrapped with copper. The safety wire 57 is anchored to the tip electrode 36, for example, by soldering the safety

wire 57 into the first hole 47 in the stem 37. At its proximal end, the safety wire 57 is wrapped around the compression coil 52 at a location within the catheter body 12.

[0047] An electromagnetic location sensor 72 is contained within the tip electrode 36. The electromagnetic sensor 72 is located within proximal section 31a of the blind hole 31 in the tip electrode 36 and fixed by polyurethane glue or the like. Depending on the dimensions of the tip electrode 36 and sensor 72, it may be desirable for the sensor to extend, at least in part, into the stem 37 of the tip electrode and possibly even into the distal end of the tubing 19 of the tip section. The electromagnetic sensor 72 is connected to an electromagnetic sensor cable 74, which extends through the third lumen 34 of the tip section 14, through the catheter body 12, and out through control handle 16. The electromagnetic sensor cable 74 comprises multiple wires encased within a plastic covered sheath. In the control handle 16, the sensor cable 74 is connected to a circuit board (not shown). The circuit board amplifies the signal received from the electromagnetic sensor 72 and transmits it to a computer in a form understandable by the computer. Also, because the catheter is designed for single use only, the circuit board contains an EPROM chip which shuts down the circuit board after the catheter has been used. This prevents the catheter, or at least the electromagnetic sensor, from being used twice. Suitable electromagnetic sensors for use with the present invention are described, for example, in EP-A-0 989 384 and U.S. Patent Nos. 5,558,091, 5,443,489, 5,480,422, 5,546,951, 5,568,809, and 5,391,199, the disclosures of which are incorporated herein by reference.

[0048] Longitudinal movement of the puller wire 50 relative to the catheter body 12, which results in deflection of the tip section 14, is accomplished by suitable manipulation of the control handle 16. A suitable control handle design for use with the present invention is described in EP-A-0 928 601 and EP-A-0 900 549, the disclosures of which are incorporated herein by reference.

[0049] If desired, the catheter can be multidirectional, i.e., having two or more puller wires to enhance the ability to manipulate the tip section in more than one direction or to form two or more different curves. A description of such a design is provided in EP-A-0 904 796, EP-A-0 985 423, EP-A-0 982 407, EP-A-1 005 839 and EP-A-1 038 545, the disclosures of which are incorporated herein by reference.

[0050] The catheters in accordance with the present invention are particularly suitable for mapping the heart and ablating heart tissue, such as accessory signal pathways causing arrhythmias. In operation, the distal end of the catheter 10 is inserted into a vein or artery and advanced into the heart. To assist in positioning the tip section 14 of the catheter 10 at a desired position within the heart, the puller wire 50 and control handle 16 are used to deflect the tip section 14. Once the tip section 14 has been positioned at or near the desired location of the heart tissue, the electrical activity of the

heart may be identified, evaluated or mapped, and electrophysiological sources of arrhythmia may be identified and/or treated.

[0051] More specifically the bipolar electrode pair, namely, the exposed region 35 of the tip electrode 36 and ring electrode 39 mounted on the tip electrode, is used to map the electrical activity of the heart. The close proximity of the ring electrode 39 to the exposed region 35 of the tip electrode 36 provides the catheter with more accurate bipolar mapping capabilities. Because of their close proximity, the electrodes 36 and 39 are exposed to nearly identical noise and far-field background signals. A bipolar electrogram displays the difference of the two signals, so essentially only the electrical activity from the nearby tissue is recorded. Closely spaced electrodes provide more discrete electrograms.

[0052] Additionally, the electrically insulating layer 55 limits the electrically active surface area of the tip electrode 36 to the exposed region 35, providing improved electrogram resolution compared to a conventional tip electrode. More specifically, electrograms recorded from the relatively small exposed region 35 will be more discrete, reporting electrical activity from a smaller area of tissue.

[0053] The electromagnetic location sensor 72 in the tip section 14 of the catheter is used to provide a map of the heart so that the physician can better determine where to ablate and can have a better sense for where the tip section 14 is located during the procedure. In use, the patient is placed in a magnetic field generated, for example, by situating under the patient a pad containing coils for generating a magnetic field, and a reference electromagnetic sensor is fixed relative to the patient, e.g., taped to the patient's back. Signals generated in the heart by both the fixed reference sensor and the electromagnetic location sensor 72 in the catheter are amplified and transmitted to a computer that analyzes the signals and displays them on a monitor. By this method, the precise location of the location sensor 72 (and thus the tip section 14, including the tip electrode 36) relative to the reference sensor can be ascertained and visually displayed. The sensor 72 can also detect displacement of the catheter that is caused by contraction of the heart muscle.

[0054] The electromagnetic mapping sensor 72 preferably is used in combination with the tip electrode 36 and ring electrode 39. By combining the electromagnetic sensor 72 and electrodes 36 and 39, a physician can simultaneously map the contours or shape of the heart chamber, the electrical activity of the heart, and the extent of displacement of the catheter. The tip electrode 36 and ring electrode 38 are used to monitor the strength of the electrical signals at a particular location. As would be recognized by one skilled in the art, the inventive tip electrode design can be effectively used without the inclusion of a location sensor, and thus the electromagnetic sensor 72 can be eliminated if desired.

[0055] Once the electrical activity of the heart is de-

termined and mapped, if desired, the physician uses the same catheter for ablating the heart tissue. The relatively large surface area of the tip electrode 36, which includes the exposed region 35 as well as the central region 38 covered with the thermally conductive layer 55, enhances the ability of the electrode to dissipate heat during ablation compared to a comparable tip electrode having a length closer to the that of the exposed region 35 of the present catheter. Compared to a standard 4 mm tip electrode, the tip electrode of the present invention having a preferred length (outside of the plastic tubing 19) of about 6 mm to about 8 mm provides improved convective cooling by the passing blood, such that additional power can be applied to the tissue. However, conventional 8 mm tip electrodes require more power than the inventive tip electrode. The tip electrode of the present invention preferably has an exposed length of only about 2 mm to about 3 mm, reducing the amount of power required to ablate compared to a tip electrode have an exposed length of 8 mm. Further, a conventional 8 mm tip electrode uses more energy heating the surrounding blood rather than heating the adjacent heart tissue. This heating of the blood can cause significant coagulation of the blood along the surface of the tip electrode. The present invention overcomes this problem by providing an electrically insulating, but thermally conductive layer over the non-exposed portion of the tip electrode 36, allowing the electrical power to be concentrated at the exposed region 35, while the insulated portion (the central region 38) of the tip electrode is convectively cooled by passing blood.

[0056] As a result of this design, more power can be applied to the tissue with the inventive electrode compared to a standard tip electrode having a total length equal to the length of the exposed region 35 of the inventive electrode. This holds true because the blood can more efficiently cool the inventive electrode compared to the standard tip electrode. Additionally, the inventive electrode can create the same sized lesion as a standard tip electrode having a total length equal to the total length of the inventive electrode (but without an electrically insulating and thermally conductive covering), but using less power. This holds true because the inventive electrode has a higher current density than a standard tip electrode, while still having similar cooling capabilities, and therefore less power is needed.

[0057] Additionally, as discussed above, electrode impedance is routinely monitored during ablation to detect the potential formation of dangerous char or thrombus on the tip electrode. Because the electrically active area (i.e., the exposed region 35) of the inventive tip electrode is smaller than with conventional ablation tip electrodes that offer similar cooling ability, changes in impedance due to char or thrombus formation are more readily detected with the inventive catheter.

[0058] The preceding description has been presented with reference to presently preferred embodiments of the invention. Workers skilled in the art and technology

to which this invention pertains will appreciate that alterations and changes in the described structure may be practiced without meaningfully departing from the principal, spirit and scope of this invention.

[0059] Accordingly, the foregoing description should not be read as pertaining only to the precise structures described and illustrated in the accompanying drawings, but rather should be read consistent with and as support to the following claims which are to have their fullest and fair scope.

Claims

1. A catheter comprising: 15
 - an elongated flexible body having a distal region and at least one lumen extending there-through;
 - a tip electrode mounted on the distal region, the 20
 - tip electrode having an exposed distal region having proximal and distal ends and an isolated region proximal to the exposed distal region, wherein the isolated region has an outer surface provided with an electrically insulating and 25
 - thermally conductive layer; and
 - a second electrode mounted on the isolated region on the tip electrode.
2. A catheter as claimed in claim 1, wherein the second electrode is a ring electrode. 30
3. A catheter as claimed in claim 1 or claim 2, wherein the total length of the exposed distal region and the isolated region ranges from 4 mm to 12 mm, preferably from 6 mm to 10 mm. 35
4. A catheter as claimed in any one of claims 1 to 3, wherein the exposed distal region has a length ranging from 1.5 mm to 4.0 mm, preferably from 2 mm to 3 mm. 40
5. A catheter as claimed in any one of claims 1 to 4, wherein the second electrode is mounted a distance from the proximal end of the exposed region 45
 - no more than about 2mm.
6. A catheter as claimed in any one of claims 1 to 5, wherein the second electrode is mounted a distance from the distal end of the catheter body 50
 - no more than about 2 mm.
7. A catheter as claimed in any one of claims 1 to 6, wherein the electrically insulating and thermally 55
 - conductive layer comprises a composition selected from the group consisting of diamond, carbon, parylene, polyimide, polyester, polyurethane, epoxy, ceramic, and combinations thereof.
8. A catheter as claimed in any one of claims 1 to 7, wherein the electrically insulating and thermally 16
 - conductive layer has a thickness no greater than about 10 μm , preferably ranging from 1 μm to 5 μm .
9. A catheter as claimed in any one of claims 1 to 8, wherein the isolated region has an outer diameter less than the outer diameter of the exposed region.
10. A catheter as claimed in any one of claims 1 to 9, wherein the exposed region has a length approximately equal to its outer diameter.

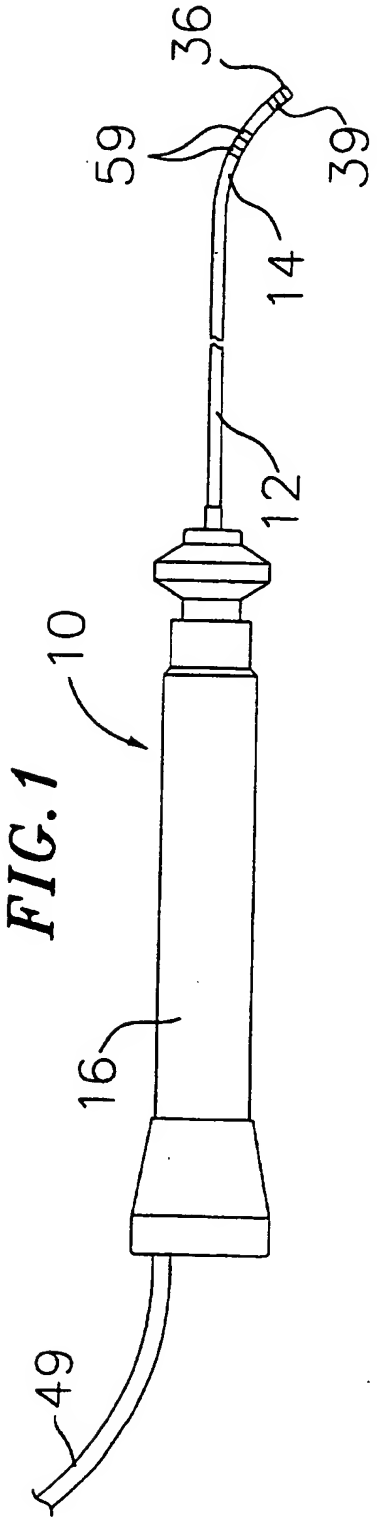


FIG. 2

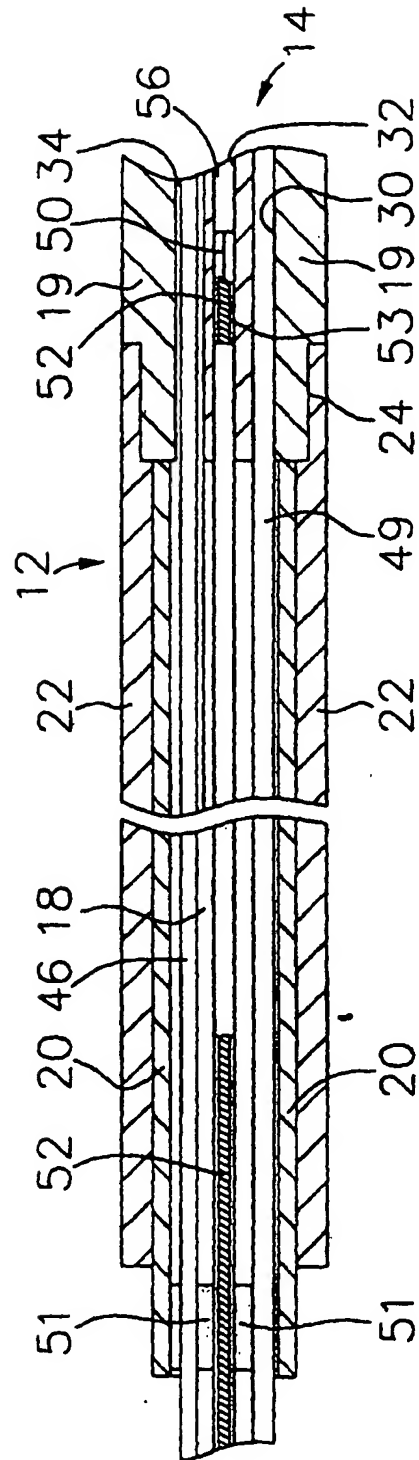


FIG. 3A

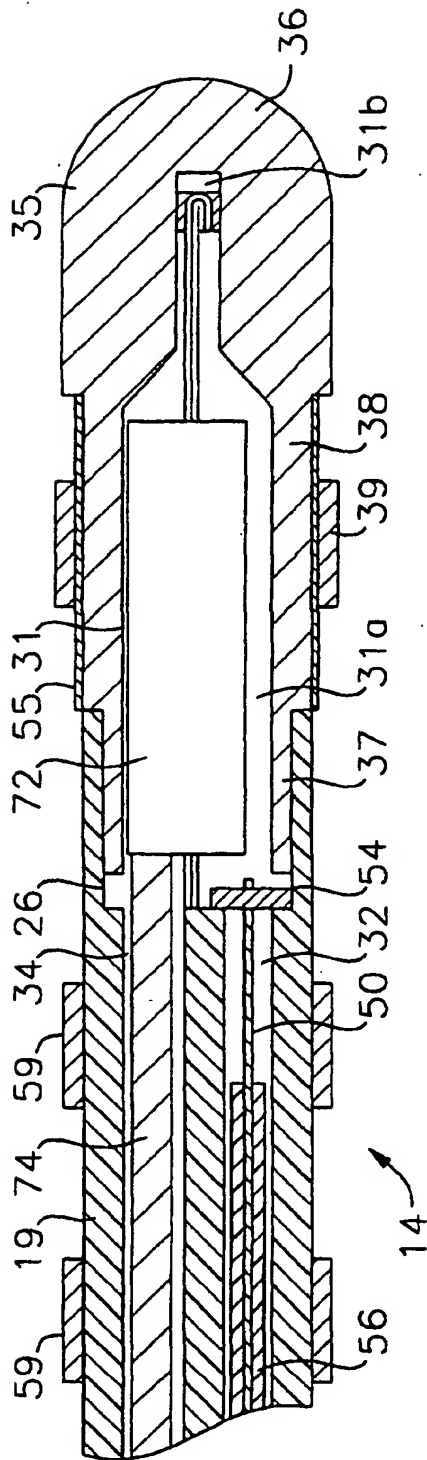
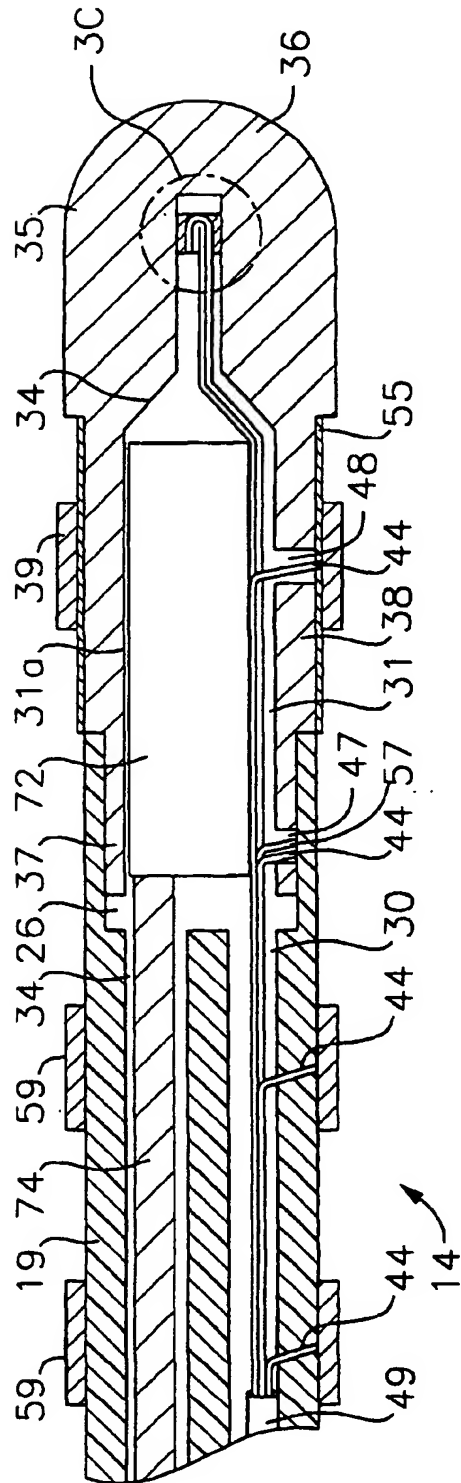
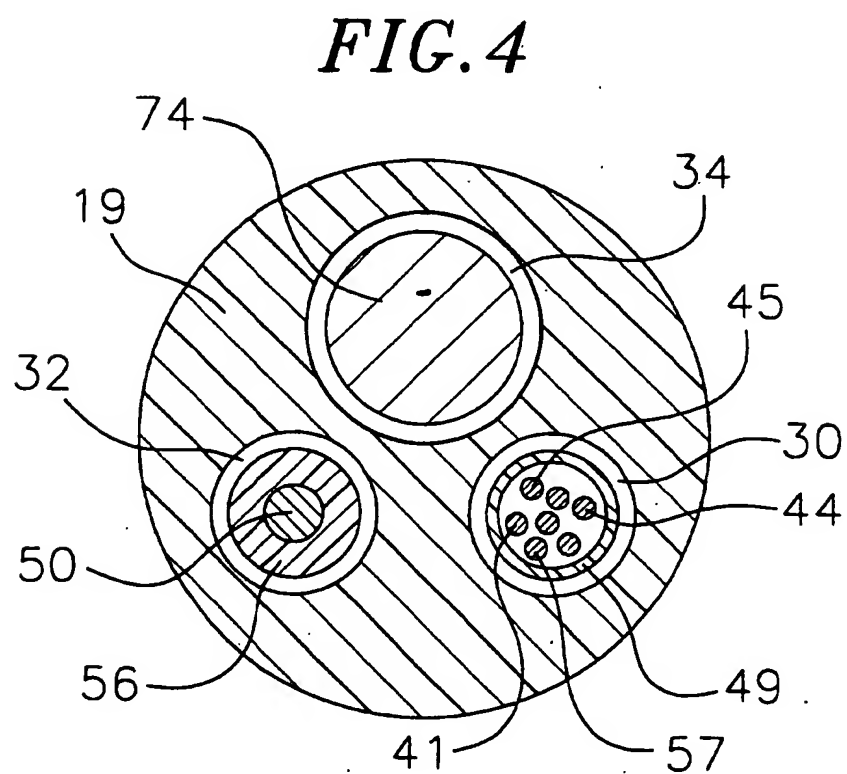
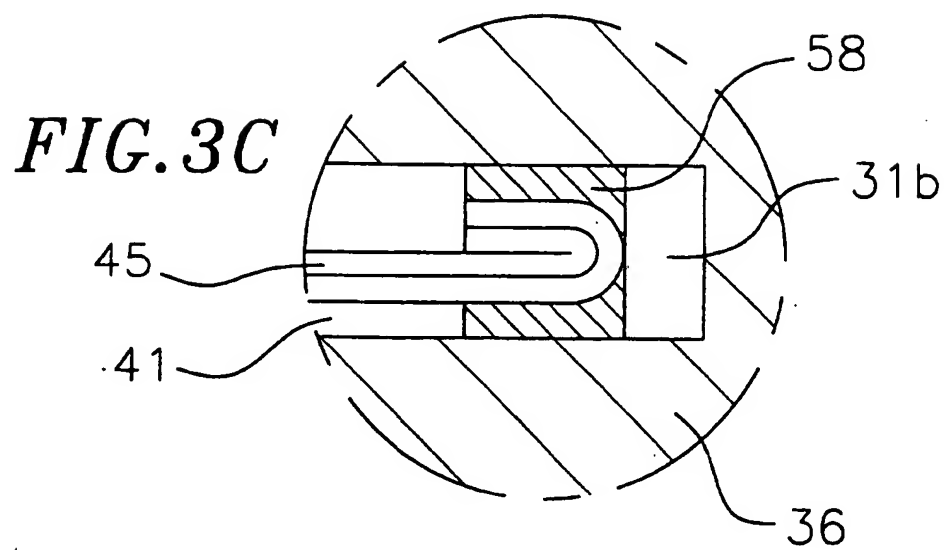


FIG. 3B







European Patent
Office

EUROPEAN SEARCH REPORT

Application Number
EP 01 30 5844

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
A	US 5 545 161 A (IMRAN MIR A) 13 August 1996 (1996-08-13) ---		A61B18/14
A	US 5 257 635 A (LANGBERG EDWIN) 2 November 1993 (1993-11-02) -----		
			TECHNICAL FIELDS SEARCHED (Int.Cl.7)
			A61B
The present search report has been drawn up for all claims			
Place of search THE HAGUE		Date of completion of the search 25 September 2001	Examiner Papone, F
<p>CATEGORY OF CITED DOCUMENTS</p> <p>X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document</p> <p>T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document</p>			

EPO FORM 1503 03.82 (PatCo1)

**ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.**

EP 01 30 5844

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

25-09-2001

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 5545161	A	13-08-1996	US 5697927 A	16-12-1997
			US 5348554 A	20-09-1994
			AU 673015 B2	24-10-1996
			AU 5201993 A	16-06-1994
			CA 2110309 A1	02-06-1994
			EP 0608609 A2	03-08-1994
			JP 2562861 B2	11-12-1996
			JP 6254103 A	13-09-1994
			US 5423811 A	13-06-1995
			US 5658278 A	19-08-1997
US 5257635	A	02-11-1993	US 4945912 A	07-08-1990
			AT 150274 T	15-04-1997
			AU 4187893 A	23-09-1993
			AU 645486 B2	20-01-1994
			AU 4660189 A	26-06-1990
			CA 2003689 A1	25-05-1990
			DE 68927892 D1	24-04-1997
			EP 0445223 A1	11-09-1991
			EP 0745354 A2	04-12-1996
			WO 9006079 A1	14-06-1990
			US 5370644 A	06-12-1994
			US 5246438 A	21-09-1993
			US 5230349 A	27-07-1993
			CA 2070403 A1	04-02-1992
			EP 0497959 A1	12-08-1992
			WO 9202272 A1	20-02-1992

EPO FORM P449

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

THIS PAGE BLANK (USPTO)